Additive manufacturing of customized lower limb orthoses – A review

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Abstract

Additive manufacturing (AM) has been successfully applied in the healthcare and shows potential for modernization of lower limb orthoses manufacturing process. This study aims to analyze the scientific production of AM application in customized lower limb orthoses production (foot and ankle-foot orthoses) to identify possible research gaps. To reach the proposed objective, a systematic literature review was carried out, based on the construction of a bibliographic portfolio, a bibliometric study and on article content analysis. Some study gaps were identified as the cost of the 3D digitalizing and the additive manufacturing process employed. This review will be the basis for the development of research on the application of low cost 3D digitizing and 3D printing technologies in the development of lower limb orthoses.

Keywords: additive manufacturing; assistive technology; 3D printing; medical applications.

1. Introduction

Orthoses are assistive devices that, according to the need of patients with neuromuscular and musculoskeletal deficiencies, can: maintain or correct the alignment of a segment of the body, restrict joint movement, distribute forces and minimize the risk of deformities, therefore contributing to improve quality of life.[1]

Lower limb orthoses prescription is very common for children, due to the occurrence of muscular dystrophies, dysfunctions and pathologies during motor development.[2]

After an analysis of the manufacturing process of customized lower limb orthoses in Brazil, described in the booklet developed by the Ministry of Health, traditional method were found to be time-consuming, generators of large amounts of plaster waste;[3] they need specialized labor and may also cause discomfort in patients during the molding phase.[1]

Additive manufacturing (AM) - also known as 3D printing - is a manufacturing process that is based on the construction of the part layer by layer. It involves technologies that allow complex geometries printing, both in large and low scale production.[4] There are several construction techniques, each with specific materials and particularities.

In Selective Laser Sintering (SLS), the powder material is added layer by layer and sintered or fused using a laser. In Stereolithography (SLA), a movable platform immersed in a vat with a photocuring resin is moved incrementally so that an ultraviolet laser cures the desired regions. In Material Extrusion (ME), a filament of polymeric material is heated and extruded to form the product.[5]

AM has already been applied in the healthcare: in surgery teaching and planning,[6,7] in tissue engineering,[8,9] and in the manufacturing of diverse products[10]. This technology is relatively recent, with approximately 25 years, and has already been used orthoses and prostheses manufacturing.[11]

In customized orthoses manufacturing, it is necessary to obtain the limb geometry. This can be accomplished through 3D digitizing of the limb, also known as direct scanning; or through 3D digitizing of a limb model, known as indirect scanning. This model can be made of plaster, for example.[12]

The objective of this study is to analyze the scientific production and look for possible research gaps related to the application of additive manufacturing in lower limb orthoses production, with emphasis on foot (FO) and ankle-foot (AFO) orthoses. A bibliographic review, using bibliometrics to facilitate result filtering and gap identification, is therefore justified.

2. Materials and Methods

A computer with access to the CAPES Portal databases was used for this study, as well as some software tools, such as Mendeley Desktop for article management, and Microsoft Excel for result tabulation. The Knowledge Development Process-Constructivist method, known as Proknow-C, was developed at the Laboratory of Multicriteria Methodologies in Decision Support (LabMCDA) of the Federal University of Santa Catarina, aiming to form a structured process for selecting and analyzing literature in a scientific research. This method involves bibliographic portfolio selection, a bibliometric analysis and a systemic analysis to define the research question and the research's general and specific objectives.[13]

Therefore, this study is characterized as a systematic review, contemplating a bibliographic portfolio on the research topic, a bibliometric analysis of this portfolio a content analysis of the articles to identify research gaps.

The bibliographic portfolio was obtained through the following steps.

1) Select databases of interest;

The selected databases were: Web of Science, Scopus, IEEE Xplorer, Science Direct and PubMed.

2) Define research axes and keywords;

The chosen research axes were: additive manufacturing and lower limb orthoses. In the first axis, the keywords include additive manufacturing process and 3D digitizing. In the second axis, the keywords referred to applications in lower limb orthoses.

The search algorithm was defined using the Boolean operators "OR" for items of the same axis and "AND" between axes.

The search algorithm formed with these keywords was: ("rapid prototyp*" OR "additive manufactur*" OR "freeform prototyp*" OR "3D print*" OR "tree-dimensional printing" OR "3D scan*" OR "3D digit*") AND ("foot orthos*" OR "custom* foot orthos*" OR "lower limb orthos*" OR "pedorthos*").

3) Execute the search in databases;
4) Apply filters in results to find publications of interest;
5) Carry out a bibliometric analysis of the bibliographic portfolio obtained;
6) Analyze the content of the publications to identify the study gaps.

3. Results

3.1 Bibliographic Portfolio

The search in the databases was performed after the algorithm definition, and 140 raw articles were obtained. The results distribution according to each database is shown in Figure 1.

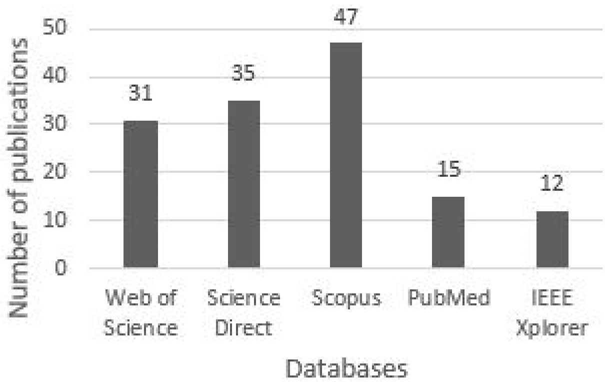

Figure 1. Number of publications per database

Filters were applied to the results, in order to refine the search. To verify the appropriateness of the results in relation to the search objective, the individual article titles in each database were read, reducing the results to 80. The abstracts were then read, which resulted in 71 remaining publications. The free access article filter was applied which led to 54 remaining publications.

The duplicate references were then removed using the Mendeley Desktop database, where 29 references were obtained. From this point, the articles were read entirely in order to analyze the contents, resulting in 20 remaining publications that were considered the most appropriate. The references were tabulated in Microsoft Excel.

Considering that additive manufacturing is a relatively new concept, it was decided not to apply any filters relative to the number of citations or the publication year. The bibliographic portfolio obtained is shown in Table 1.

Table 1 Bibliographic Portfolio obtained

Titles	Journal/Conference	Citations
Additive manufacturing of custom orthoses and prostheses—A review[11]	Additive Manufacturing	7
Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint[14]	Cogent Engineering	0
Process Planning for the Fuse Deposition Modeling of Ankle-Foot-Othoses[1]	Procedia CIRP	7
Innovations With 3-Dimensional Printing in Physical Medicine and Rehabilitation: A Review of the Literature[10]	PM&R	1
The influence of passive-dynamic ankle-foot orthosis bending axis location on gait performance in individuals with lower-limb impairments[15]	Clinical Biomechanics	5
Additive Manufacturing of Custom Orthoses and Prostheses – A Review[16]	Procedia CIRP	17
Fused Deposition Modelling Technique (Fdm) for Fabrication of Custom-Made Foot Orthoses: a Cost and Benefit Analysis[17]	Science International	3
Newly Design Foot Orthosis for children with residual Clubfoot after Ponseti Casting[18]	Journal of Prosthetics & Orthotics	3
The influence of ankle-foot orthosis stiffness on walking performance in individuals with lower-limb impairments[19]	Clinical Biomechanics	17
The use of a low cost 3D scanning and printing tool in the manufacture of custom-made foot orthoses: a preliminary study[20]	BMC research	27
Functionally optimized orthoses for early rheumatoid arthritis foot disease: A study of mechanisms and patient experience[21]	Arthritis Care & Research	10
Gait assessment during the initial fitting of customized selective laser sintering ankle foot orthoses in subjects with drop foot[22]	Prosthetics and Orthotics International	19
Development of dynamic ankle foot orthosis for therapeutic application[23]	Procedia Engineering	9
Embracing additive manufacture: implications for foot and	BMC Musculoskeletal	39

ankle orthosis design[24]	Disorders	
Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework[25]	Journal of Rehabilitation Research and Development	43
Patient specific ankle-foot orthoses using rapid prototyping [26]	Journal of NeuroEngineering and Rehabilitation	57
Additive fabrication of custom pedorthoses for clubfoot correction[27]	Rapid Prototyping Journal	15
Design and additive fabrication of foot and ankle-foot orthoses[28]	21st Annual International Solid Freeform Fabrication Symposium	19
Mass customization of foot orthoses for rheumatoid arthritis using selective laser sintering[29]	IEEE Transactions on Biomedical Engineering	70
Manufacture of Passive Dynamic ankle-foot orthoses using selective laser sintering[30]	IEEE Transactions on Biomedical Engineering	104

3.2 Bibliometric Analysis

From data tabulation, a bibliometric study was conducted regarding the most important factors for this research. Figure 2 illustrates the evolution of the number of publications per year. It was noticed that even though publication year filters were not applied, the results obtained are composed of publications from the last 10 years. Although the data collection was carried out in April 2017, no publications on the matter were found for this year.

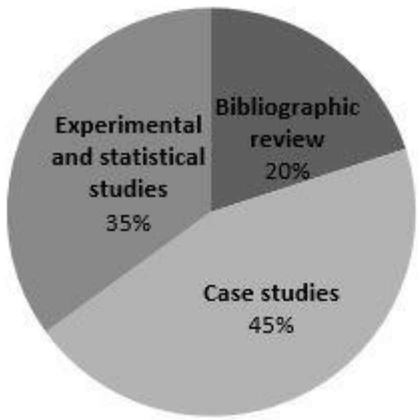

Figure 2. Number of publications per year

It should be noted that 2016 is the year with the largest number of article publications on the research topic, with 5 articles published, proving this to be a contemporary theme.

Regarding the journal in which the articles were published, three journals returned more than one publication in the search: Clinical Biomechanics, Procedia CIRP and IEEE Transactions Biomedical Engineering; they returned two publications each. It should be noted that the articles published in IEEE Transactions Biomedical Engineering are the oldest registered in the portfolio and, therefore, the most cited.

This made it possible to notice that the authors do not have preference for a specific periodical or area. The journals were from different areas, such as: mechanical engineering, biomedical engineering, physical education, among others. This was probably due to the multidisciplinary nature of the theme.

3.3 Content Analysis

Four articles from the obtained portfolio were bibliography reviews. Chen et al. and Jin et al. reviewed the literature on the use of additive manufacturing in orthoses and prostheses in general.[11, 16] Lunsford et al. analyzed the scientific production regarding the application of AM in rehabilitation.[10] Pallari et al. analyzed what was done to optimize the manufacturing process of foot and ankle-foot orthoses through additive manufacturing.[28]

Eight studies were conducted with only one patient or with only one orthosis produced.[14, 17, 20, 23, 24, 26, 27, 30] Among these studies, four were conducted with healthy patients.[14, 20, 24, 26] Seven articles involved studies and experiments applied in more than one patient with some type of lesion or deformity and had statistical analysis applied.[15, 18, 19, 21, 22, 25, 29] Only one study was conducted with children with foot deformities.[18]

Figure 3 illustrates the number of articles according to the following classification: bibliographic review, case studies (one patient, healthy or not) and experimental and statistical studies.

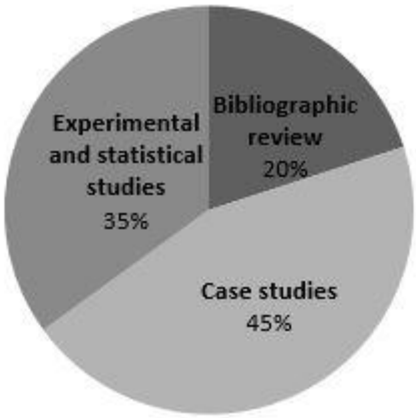

Figure 3. Articles classification

Regarding the additive manufacturing process, Figure 4 illustrates the number of studies developed using Selective Laser Sintering (SLS), Material Extrusion (ME) and Stereolithography (SLA). It is important to emphasize that most of the authors explored the Selective Laser Sintering technology.

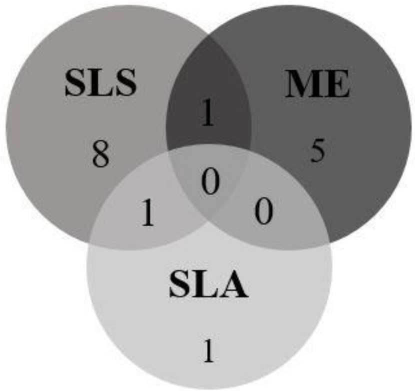

Figure 4. Quantification of Additive Manufacturing processes used by authors

It was also observed that nylon was the most used material in the Selective Laser Sintering and ABS in Material Extrusion. Table 2 summarizes the articles in terms of the author, year of publication, type of orthosis produced, additive manufacturing and digitizing process employed and orthoses material. Table 2 does not include the four bibliographic review articles.

Patients using printed orthoses reported equal or greater comfort sensation compared to orthoses manufactured by the traditional method.[21, 22, 27] Clinical performance was similar between printed and traditional orthoses in two studies.[24, 26]

Some of the problems were reported by Pallari, Dalgarno and Woodburn, who cite difficulties regarding the lack of specific software for orthoses design, which makes mass production difficult.[29] Jumani et al. proposed to analyze the costs involved in customized orthoses manufacturing through material extrusion and stated that, until 2014, they were larger than those manufactured by the traditional method.[17]

Jin, He and Shih demonstrated the importance of planning the manufacturing process of an ankle-foot orthosis, in which variables influence the strength of the orthosis, its surface finish, the construction time and the amount of support material.[1]

Table 2 Summary of studies applying Additive Manufacturing in the manufacture of foot and ankle-foot orthoses

Reference	Produced Orthoses	AM Process	Digitizing Process	Material
[14]	AFO	ME	Direct scanning	ABS
[15]	AFO	SLS	Not informed	Nylon 11
[16]	AFO	ME	Not informed	Not informed
[17]	FO	ME	Not informed	ABS
[18]	FO	SLS	Computed tomography	Not informed
[19]	AFO	SLS	Not informed	Nylon 11
[20]	FO	ME	Direct scanning using Microsoft Kinect	ABS

[21]	FO	ME and SLS	Direct laser scanning	ME: PLA SLS: Nylon 12
[22]	AFO	SLS	Direct laser scanning	Nylon 12
[23]	AFO	ME	Not informed	ABS
[24]	FO and AFO	SLS	FO: Direct scanning AFO: Indirect laser scanning	Nylon 12
[25]	AFO	SLS	Direct laser scanning	DuraForm EX
[26]	AFO	SLA	Direct laser scanning	ACCURA 40 and DSM Somos 9120 Epoxy
[27]	FO	SLS and SLA	Not informed	SLS: Nylon SLA: silicone
[29]	FO	SLS	Direct laser scanning	Nylon 12
[30]	AFO	SLS	Computed tomography indirectly from an orthosis	Nylon 11 Nylon 12 Nylon 12 *glass-filled*

4. Discussion

4.1 Identified gaps

The research opportunities identified were:

a) Few studies have been conducted with children. Liu et al. were the only authors to develop an orthosis for a child with feet deformity.[18] The challenges associated with the digitization of children's lower limbs with cognitive preserved or not, still need to be studied.

b) Pallari, Dalgarno and Woodburn defined standardized procedures for mass production of lower limb orthoses using Selective Laser Sintering.[29] Methods for process automation and feasibility for industrial scale have not yet been developed for other techniques.

c) Despite the advantages reported by Schrank and Stanhope regarding the SLS manufacturing orthoses costs being a function of the printed volume and allowing complex geometries printing,[25] this technique is not financially feasible for most Brazilian clinics, in emerging countries or underdeveloped countries, due to its high cost. Low-cost techniques for 3D printing may be feasible.

d) Most of the digitizing techniques used had a high cost (laser scanning or computed tomography). Only one study explored lower cost techniques such as Microsoft Kinect.[20] Therefore, there is an opportunity to apply lower-cost scanning techniques.

e) As reported by Pallari et al., the freedom of geometry allowed by additive manufacturing was explored for Selective Laser Sintering.[28] There are still many study opportunities regarding project optimization for other printing techniques, since they have their own peculiarities.

5. Conclusions

Searching for theoretical references is of vital importance at the beginning of engineering projects. The application of the Proknow-C method made it easier to identify gaps in the literature.

By applying these concepts, it was possible to obtain a bibliographic portfolio on the application of 3D digitizing and additive manufacturing techniques in lower limb orthoses production (foot and ankle-foot orthoses). This study also made it possible to identify researchers from this field and to comprehend gaps such as: conducting studies with children with or without cognitive condition preserved; explore the AM advantage of allowing complex geometry printing using other techniques, besides Selective Laser Sintering; and procedures standardization for each 3D printing technique.

It was possible to visualize the gap that represents a possible solution for lower limb orthoses manufacturing in Brazil: the use of low cost resources for 3D printing and digitizing.

Thus, additive manufacturing shows potential for orthoses manufacturing and this study will be the basis for a research on the application of low cost 3D digitizing and printing technologies in the development of lower limb orthoses.

7. References

[1] Y. Jin, Y. He , A. Shih. “Process Planning for the Fuse Deposition Modeling of Ankle-Foot-Othoses”, Procedia CIRP, 2016, pp. 760–765.

[2] A. Vieira, M. Pereira. The use of orthotics in the Child and Adolescent Health sector of the Physiotherapy Clinic of the University of São Francisco. End of Course Project, São Franscisco University, Bragança Paulista, Brazil, 2007.

[3] Brazilian Ministry of Health. Fabrication Process of Suropodal Othoses. In: Preparation and maintenance of orthoses, prostheses and locomotion aids: confection and maintenance of lower limb prostheses, suropodal orthoses and wheelchair postural adjustment, Brasília, DF: MS Publishing Company, 2013, pp.133-152.

[4] B. Conner, G. Manogharan, A. Martof, et al. “Making sense of 3-D printing: Creating a map of additive manufacturing products and services”, Additive Manufacturing, 2014, pp. 64–76.

[5] K. Wong, A. Hernandez. “A Review of Additive Manufacturing”, ISRN Mechanical Engineering, 2012, pp. 208760–208770.

[6] A. Opolski, B. Erbano, N. Schio, et al. “Experimental Three - Dimensional Biomodel of Complex Aortic Aneurysms by Rapid Prototyping Technology”, 3D Printing and Additive Manufacturing, 2014, pp. 88-94.

[7] Y. Wu, M. Rajaraman, B. Lee, et al. “A Patient-Specific Flexible 3D Printed Orthopedic Model for Training and Teaching of Clubfoot Correction Surgery”, 3D Printing and Additive Manufacturing 2016, pp. 99-105.

[8] C. Kengla, E. Renteria, C. Wivell, et al. “Clinically Relevant Bioprinting Workflow and Imaging Process for Tissue Construct Design and Validation”, 3D Printing and Additive Manufacturing, 2016, pp. 239-247.

[9] M. Cabrera, B. Sanders, O. Goor, et al. “Computationally Designed 3D Printed Self-Expandable Polymer Stents with Biodegradation Capacity for Minimally Invasive Heart Valve Implantation: A Proof-of-Concept Study”, 3D Printing and Additive Manufacturing, 2017, pp. 19-29.

[10] C. Lunsford, G. Grindle, B. Salatin, et al. “Innovations With 3-Dimensional Printing in Physical Medicine and Rehabilitation: A Review of the Literature”, PM and R, 2016, pp. 1201–1212.

[11] R. Chen, Y. Jin, J. Wensman, et al. “Additive manufacturing of custom orthoses and prostheses-A review”, Additive Manufacturing, 2016, pp. 77–89.

[12] M. Salmi, J. Tuomi, R. Sirkkanen, et al. “Rapid Tooling Method for Soft Customized Removable Oral Appliances”, The Open Dentistry Journal, 2012, pp. 85–89.

[13] L. Ensslin. “Research Process and Bibliometric Analysis: Bank Service Quality Assessment”, Revista Administração Contemporânea, 2013, pp. 325–349.

[14] M. Walbran, K. Turner, A. McDaid. “Customized 3D printed ankle-foot orthosis with adaptable carbon fibre composite spring joint”, Cogent Engineering, 2016, pp. 1-11.

[15] E. Ranz, E. Esposito, J. Wilken, et al. “The influence of passive-dynamic ankle-foot orthosis bending axis location on gait performance in individuals with lower-limb impairments”, Clinical Biomechanics, 2016, pp. 13–21.

[16] Y. Jin, J. Plott, R. Chen, et al. “Additive manufacturing of custom orthoses and prostheses - A review”, Procedia CIRP, 2015, pp. 199–204.

[17] M. Jumani, S. Shaikh, S. Shah. “Fused Deposition Modelling Technique (Fdm) for Fabrication of Custom-Made Foot Orthoses: a Cost and Benefit Analysis”, Sci-Int.Com, 2014, pp. 2571–2576.

[18] X. Liu, C. Tassone, R. Rizza, et al. “Newly Design Foot Orthosis for children with residual Clubfoot after Ponseti Casting”, JPO Journal of Prosthetics and Orthotics, 2014, pp. 38–42.

[19] N. Harper, E. Esposito, J. Wilken, et al. “The influence of ankle-foot orthosis stiffness on walking performance in individuals with lower-limb impairments”, Clinical Biomechanics, 2014, pp. 877–884.

[20] C. Dombroski, M. Balsdon, A. Froats. “The use of a low cost 3D scanning and printing tool in the manufacture of custom-made foot orthoses: a preliminary study”, BMC Research Notes, 2014, pp. 443-446.

[21] K. Gibson, J. Woodburn, D. Porter, et al. “Functionally optimized orthoses for early rheumatoid arthritis foot disease: A study of mechanisms and patient experience”, Arthritis Care and Research, 2014, pp. 1456–1464.

[22] V. Creylman, L. Muraru, J. Pallari, et al. “Gait assessment during the initial fitting of customized selective laser sintering ankle foot orthoses in subjects with drop foot”, Prosthetics and Orthotics International, 2013, pp. 132–138.

[23] A. Patar, N. Jamlus, K. Makhtar, et al. “Development of dynamic ankle foot orthosis for therapeutic application”, Procedia Engineering, 2012, pp. 1432–1440.

[24] S. Telfer, J. Pallari, J. Munguia, et al. “Embracing additive manufacture: implications for foot and ankle orthosis design”. BMC Musculoskeletal Disorders, 2012, pp. 84-93.

[25] E. Schrank, S. Stanhope. “Dimensional accuracy of ankle-foot orthoses constructed by rapid customization and manufacturing framework”, Journal of Rehabilitation Research and Development, 2011, pp. 31–42.

[26] C. Mavroidis, R. Ranky, M. Sivak, et al. “Patient specific ankle-foot orthoses using rapid prototyping”, Journal of Neuroengineering and Rehabilitation, 2011, pp. 1-11.

[27] D. Cook, V. Gervasi, R. Rizza, et al. “Additive fabrication of custom pedorthoses for clubfoot correction”, Rapid Prototyping Journal, 2010, pp. 189–193.

[28] J. Pallari, K. Dalgarno, J. Munguia, L, et al. “Design and additive fabrication of foot and ankle-foot orhtoses”. In: Proceedings of the 21st International Solid Freeform Fabrication Symposium, Austin, United States of America, 2010, pp. 834–845.

[29] J. Pallari, K. Dalgarno, J. Woodburn. “Mass customization of foot orthoses for rheumatoid arthritis using selective laser sintering”, IEEE Transactions on Biomedical Engineering, 2010, pp. 1750–1756.

[30] M. Faustini, R. Neptune, R. Crawford, et al. “Manufacture of Passive Dynamic ankle-foot orthoses using selective laser sintering”, IEEE Transactions on Biomedical Engineering, 2008, pp. 784–790.